Department of Labor and Industries
Office of the Medical Director
7273 Linderson Way SW
PO Box 44321
Olympia WA 98504-4321

MEDICAL DEVICE COVERAGE REQUEST

Information provided will be used by the Office of the Medical Director in evaluating the medical device.

Your Name:	Company Name:
Mailing Address:	Date
City State ZIP + 4	FAX Number: ( )
Telephone Number: ( )	E-Mail Address:
Name of Device:	Manufacturer of Device:

Please provide answers on a separate sheet. Number answers to correspond to numbered questions.

1 a. Why do you believe this device merits consideration and review by the Office of the Medical Director?
b. What is the device intended to do?

2 a. What published, peer-reviewed literature documents the efficacy of this device or the science that underlies it?
Please enclose articles or a bibliography
b. Specify which, if any, of the enclosed articles look at the clinical effectiveness of the device and its impact on return to work of injured workers.
c. Are there any other sources that would provide useful information?
Please enclose or provide bibliography

3. FDA approval:
a. Does the device have FDA approval?
b. When was the device approved?
c. For what indications is the device approved for by the FDA?
d. What approval process was employed (e.g., 510(k), PMA, IDE)?
If approved under the 510(k) process, what device is it substantially equivalent to?
Please include approval letter and other relevant supporting documents to or from the FDA.

4. How is this device (1) different from and (2) more efficacious than devices that currently address the medical conditions for which this device has been approved?

5. How is this device (1) different from and (2) more efficacious than current medical treatment procedures or diagnostic alternatives for this type of injury?

6. Total cost for the device:
a. What is the total cost for the device for which the Department of Labor and Industries will be charged?

c. How does this cost compare with other medical treatment procedures or diagnostic alternatives for this type of injury?

7. How would this device increase the quality of care the Washington State workers would receive?

8. How would this device return Washington State workers to work more quickly than existing devices and medical treatment procedures currently do?

9. Which State Workers' compensation programs reimburse for use of this device?
Please provide contact names and phone numbers

10. Which private insurers reimburse for use of this device?
Please provide contact names and phone numbers

11. Have any relevant medical organizations (e.g., AMA) expressed an opinion on this device?
If so, please provide verification documents and contact names and numbers if possible.

12. What safety and efficacy issues does use of this device raise?

For OMD Use	Date Received:	OMD Personnel
Action:		Submitter Advised/Date:
Comments:		